REMARKS

Claims 1 to 38, as amended, appear in this application for the Examiner's review and consideration. Claims 8-28 have been withdrawn from consideration, as being drawn to non-elected subject matter. Claims 1-7 and 29-38 are currently rejected. Claims 6 and 34 have been amended, support for the amendment can be found in the specification on page 13, table 1, and on page 16, table 2.

1. Claims 1-7 and 29-38 are rejected under 35 U.S.C. 102(a), (b) and/or (e) as being anticipated.

The Examiner has rejected claims 1-7 and 29-38 as being anticipated by Vercer et al., Kotar et al., Choi et al., Nohara et al., Kato et al., and Avrutov et al. I, and II. According to the Examiner the cited references specifically disclose the claimed compound and compositions. Further, the Examiner asserts that a novel chemical product is identified first by its "chemical nature", i.e. elemental and atom content, and that it is a well known fact that many pharmaceutical solids exhibit polymorphism. According to the Examiner polymorphs are different arrangements and/or different conformations of the **same pure substance**. The Examiner alleges that applicant's arguments do not take place of objective evidence showing the alleged "stable" compound is any different from the prior art.

In response, Applicants submit that, as recited in claims 1 to 7, the presently claimed invention is directed to a chemically stable lansoprazole, either comprising between 500 ppm to 3000 ppm water, 300 ppm and 5000 ppm alcohol or a combination thereof, which may be prepared by the process of the invention. As recited in claims 29-38, the presently claimed invention is directed to a pharmaceutical composition comprising such chemically stable lansoprazole.

In contrast to the Examiner's assertions the claimed invention is not to a chemically pure substance or a particular crystalline polymorph thereof but to a stable lansoprazole which contains water and/or ("process") alcohol in the recited ranges as described in the specification. The present claims and the specification and claims, as originally filed, are clearly <u>not</u> directed to only chemically pure substances. Instead, as originally filed, each of the claims requires that the claimed stable lansoprazole compound further comprises at least a

specified amount of water and/or a specified amount of alcohol. For example, claim 1, as originally filed, recites:

> 1. A stable lansoprazole compound, further comprising greater than 500 ppm and not more than about 3,000 ppm water.

Similarly, claim 3, as originally filed, recites:

> 3. A stable lansoprazole compound, further comprising greater than 200 ppm and not more than about 5,000 ppm alcohol.

Moreover, claim 5, as originally filed, recited,

> 5. A stable lansoprazole compound, further comprising greater than 500 ppm and not more than about 3,000 ppm water, and greater than 200 ppm and not more than about 5,000 ppm alcohol.

In addition to water and alcohol, the claims, as originally filed, also recite the presence of other impurities. For example, claim 6, as originally filed, recites:

> 6. The stable lansoprazole compound as in one of claims 1 to 5, further comprising less than about 0.1% (wt/wt) sulfone derivative and less than about 0.1% (wt/wt) sulfide derivative.

Therefore, the original claims were not drawn to the compounds only. That is the originally filed claims were not directed to a chemically pure lansoprazole compound. Instead, the originally filed claims were drawn to a stable lansoprazole compound comprising at least one impurity.

Moreover, one of ordinary skill in the art, in light of the present specification, would clearly understand that the present invention is directed to a stable lansoprazole that further comprises at least water and/or alcohol. For example, the present specification, at page 1, line 11 to 14, in the Field of the Invention section states

> The present invention relates to a stable 2-(2-pyridylmethyl) sulfinyl-1*H*-benzimidazole (lansoprazole) compound, further comprising either greater than 500 ppm and not more than about 3,000 ppm water, or greater than 200 ppm and not more than about 5,000 ppm alcohol or both.

Similarly, the Summary of the Invention, at page 3, line 32, to page 4, line 11, states

> The present invention provides a stable lansoprazole compound, further comprising greater than 500 ppm and not more than about 3,000 ppm water. Preferably, the stable lansoprazole compound

> comprises greater than about 600 ppm and not more than about 3,000 ppm water.
>
> The present invention provides a stable lansoprazole compound, further comprising greater than 200 ppm and not more than about 5,000 ppm alcohol. Preferably, the stable lansoprazole compound comprises greater than about 300 ppm and not more than about 5,000 ppm alcohol.
>
> The present invention provides a stable lansoprazole compound, further comprising greater than 500 ppm and not more than about 3,000 ppm water and greater than [ ] 200 ppm and not more than about 5,000 ppm alcohol.

The specification also clearly teaches that the stable lansoprazole compound of the invention may include other impurities in addition to water and alcohol. For example, at page 5, lines 17 to 19, in a disclosure of a process for purifying the lansoprazole compound of the invention, the specification states that

> the crystallized lansoprazole compound further comprises less than about 0.1% (wt/wt) sulfone derivative and less than about 0.1% sulfide derivative (wt/wt) sulfide derivative.

Similarly, at page 6, lines 11 to 19, the specification teaches:

> The present invention provides a lansoprazole substantially free of sulfone and sulfide (i.e., containing less than about 0.1% (wt/wt) sulfone derivative and less than about 0.1% (wt/wt) sulfide derivative). A "stable" lansoprazole refers to a lansoprazole that is stable (e.g., limited decomposition) under specified storage conditions (i.e., 2-8°C or 25°C at a relative humidity of up to 60% for a time period of up to about 6 months). In other words, a "stable" lansoprazole does not undergo discoloration and remains substantially free of sulfone and sulfide (i.e., containing less than about 0.1% (wt/wt) sulfone derivative and less than about 0.1% (wt/wt) sulfide derivative) under these specified storage conditions.

Other disclosures of possible impurities in lansoprazole can be found in the Examples, at pages 12 to 16 of the specification. Therefore, the specification and the claims, as originally filed, clearly teach that the stable lansoprazole compound of the presently claimed invention comprises lansoprazole and at least one of water and alcohol, and that the stable lansoprazole compound of the presently claimed invention may also comprise other impurities.

The Examiner has apparently elected to define the term "compound" in an extremely narrow manner. However, it is well settled law that Applicants can be their own

lexicographers, as long as terms are not defined in manner that is repugnant to common usage. In the present case, in light of the specification and the originally filed claims, one of ordinary skill in the art will understand that Applicants have elected to define "lansoprazole compound" to mean lansoprazole containing one or more impurities. In this regard, one of ordinary skill in the art will understand that, other than in minute amounts, i.e., a few atoms or molecules, a sample of any compound comprises the compound and a number of ions, atoms, and/or molecules of impurities. It is extremely difficult, if not impossible, to remove all impurities from a bulk sample of a compound, even when the sample is as small as a few milligrams. Impurities in a compound will include those present in the environment, including gases, moisture, and particulates from the atmosphere and the environment, and reactants, solvents, and byproducts from the synthesis of the compound. Even where the compound is highly purified, impurities will be present. One millimole (0.001 mole) of a compound, having a purity of one part per trillion, will contain on the order of 6×10^8 atoms, ions, and/or molecules of impurities. One of ordinary skill in the art would clearly understand that no bulk sample of a compound is chemically pure, and, thus, free of any impurities. Therefore, the presently claimed invention and the claims, as originally filed, are not and were not directed to compounds only, as apparently defined by the Office Action dated January 16, 2007.

Although the cited prior art references may disclose lansoprazole and polymorphs of lansoprazole, the references disclose non-stable, prior art lansoprazole, not the presently claimed chemically stable lansoprazole composition.

Applicants submit that, as recited in claim 1, the presently claimed invention is directed to a chemically stable lansoprazole compound, further comprising greater than 500 ppm and not more than about 3,000 ppm water; as recited in claim 3, the presently claimed invention is directed to a chemically stable lansoprazole compound, further comprising greater than 200 ppm and not more than about 5,000 ppm alcohol; and, as recited in claim 5, the presently claimed invention is directed to a chemically stable lansoprazole compound, further comprising greater than 500 ppm and not more than about 3,000 ppm water, and greater than 200 ppm and not more than about 5,000 ppm alcohol. Applicants also submit that, as recited in claim 29 to 38, the presently claimed invention is directed to pharmaceutical compositions, comprising the chemically stable lansoprazole compositions of claims 1, 3, and/or 5 and a pharmaceutically acceptable excipient.

As demonstrated by Examples 2 and 3 and Table 2 of the present specification, the presently claimed chemically stable lansoprazole compound is substantially more chemically stable than prior art lansoprazole. After three months at 40°C and a relative humidity of 75 percent, the stable lansoprazole composition of the invention contains only 0.02 percent of the sulfide compound and 0.03 percent of the sulfone compound, and remains white. In contrast, under the same conditions, the non-stabilized, prior art lansoprazole contains 0.04 percent of the sulfide compound and 0.06 percent of the sulfone compound, and has changed color. Present specification, Examples 2 and 3, pages 12 to 16, and Table 2, page 16.

In contrast to the presently claimed invention, Vrečer discloses the relative physical stability of polymorphic forms A and B of prior art lansoprazole. In particular, Vrečer discloses that lansoprazole polymorphic form B is not physically stable, and transforms to polymorphic form A on heating. Vrečer discloses only non-stable, prior art lansoprazole, and, thus, Vrečer does not disclose a chemically stable lansoprazole composition, as presently claimed as Vrečer does not stabilize its crystalline lansoprazole to provide chemically stability. Therefore, Vrečer does not anticipate the present claims.

Similarly, Kotar discloses the analysis of polymorphs of prior art lansoprazole, and that lansoprazole form B is not stable, undergoing a solid-solid transition to form A. For the same reasons with respect to Vrečer, Kotar discloses only non-stable, prior art lansoprazole, and, thus, Kotar does not disclose the presently claimed chemically stable lansoprazole composition, and, thus, does not anticipate the present claims.

Choi discloses a process for preparing conventional prior art sulfoxide compounds, such as lansoprazole, comprising oxidizing a sulfide compound with hydrogen peroxide in the presence of a rhenium catalyst. The disclosed process reportedly minimizes the production of N-oxide and sulfone byproducts. Page 1, lines 4 to 17. The m-chloroperbenzoic acid, used in the prior art as the oxidizing agent, reportedly results in the formation of the N-oxide and sulfone byproducts, resulting in a low yield in the preparation. Page 3, lines 9 to 22. Other prior art processes, such as the oxidation of the sulfide compound with hydrogen peroxide in the presence of a vanadium catalyst, reportedly result in the production of more than 1 HPLC area percent of the sulfide compound and a product containing 0.4% after purification. Page 6, lines 2 to 9, and page 7, lines 1 to 11. The disclosed process reportedly minimizes the production of the N-oxide and sulfone by products, and removes the by products by filtration.

Choi discloses a non-stable, prior art lansoprazole, and, thus, does not disclose the chemically stable lansoprazole composition of the presently claimed invention. Therefore, as Choi discloses a conventional lansoprazole, not the chemically stable lansoprazole composition of the present invention, the present claims are not anticipated by Choi.

Nohara discloses 2-[2 pyridylmethylthio-(sulfinyl)-] benzimidazoles and processes for preparing such compounds. A sulfide derivative, prepared with the disclosed process, can be oxidized to prepare a sulfinyl derivative. Column 2, lines 21 to 48. Compounds produced with the disclosed process "can be isolated and purified by conventional means, e.g., crystallization and chromatography." Column 2, lines 66 to 68.

Nohara discloses only non-stable, prior art lansoprazole, and, thus, does not disclose the presently claimed chemically stable lansoprazole composition. Therefore, the present claims are not anticipated by Nohara.

Kato discloses a prior art substantially solvent-free lansoprazole that is free of decomposition in the course of vacuum drying. Column 2, lines 22 to 26. Kato specifically teaches that

> It is understood that the water content of the substantially solvent-free crystals according to the present invention is not higher than about 500 ppm, preferably not higher than about 300 ppm, and, for still better results, not higher than about 200 ppm, and the alcohol (e.g. ethanol) content is not higher than about 200 ppm, preferably not higher about 100 ppm, and, for still better results, not higher about 80 ppm. Column 7, lines 24 to 30.

Therefore, Kato does not disclose or suggest a stable lansoprazole composition, comprising chemically stable lansoprazole and greater than 500 ppm and not more than about 3,000 ppm water and/or greater than 200 ppm and not more than about 5,000 ppm alcohol, as presently claimed. Accordingly, Kato does not disclose the presently claimed chemically stable lansoprazole composition, and, thus, Kato does not anticipate the present claims.

Avrutov discloses processes for preparing substituted 2-(2-pyridylmethyl)sulfinyl-1-H-benzimidizoles. Avrutov I and II, page 1, paragraph [0002]. In particular, Avrutov discloses a selective oxidation process for preparing lansoprazole. Avrutov I, page 2, paragraph [0016]; Avrutov II, page 2, paragraph [0025].

Avrutov discloses only non-stable, prior art lansoprazole. Therefore, Avrutov does not disclose the presently claimed invention, and the present claims are not anticipated by Avrutov.

Therefore, as none of Vrečer, Kotar, Choi, Nohara, Singer, Kato, and Avrutov disclose the presently claimed invention, the present claims are not anticipated by those references. Accordingly, it is respectfully requested that the Examiner withdraw the rejection of claims 1 to 7 and 29 to 38 under 35 U.S.C. §102(a), (b), and/or (e).

2. Claims 1-7 and 29-38 were rejected under 35 U.S.C. 103(a) as being obvious.

The Examiner has rejected claims 1-7 and 29-38 as being obvious over the combined teachings of Vercer et al., Kotar et al., Choi et al., Nohara et al., Kato et al., and Avrutov et al. I, and II in view of Hableblian et al., Chemical & Engineering News, US Pharmacopeia, Muzaffar et al, Jain et al, Taday et al, Concise Encyclopedia Chemistry and Brittain et al. (Polymorphism in Pharmaceutical Solids, pages 1-2, 185). Again, according to the Examiner the cited primary references teach the stable crystal forms of the instant known compound and as well as the pharmaceutical compositions. In addition, the Examiner asserts that the remaining references teach that compounds exist in different crystalline forms and that at any particular temperature and pressure only one crystalline form is thermodynamically stable. The Examiner alleges that hence the claimed crystalline form as well as its relative selectivity of properties vis-à-vis the known compound are suggested by the references. According to the Examiner it is obvious in view of the references that the compound would exist in different stable crystalline forms. Moreover, the Examiner asserts that the claimed subject matter differs from the known product merely by forms and the physical properties innate to the forms stating that the claims are drawn to the same pure substance as the prior art that only have different arrangements and/or different conformations of the molecule.

In response, Applicants submit that the claimed invention is directed to a chemically stable lansoprazole whether crystalline or not. The method of preparing the chemically stable lansoprazole, presently claimed contains a crystallization step. However, the claimed invention is not a crystalline form of lansoprazole but a chemically stable lansoprazole. Lansoprazole is chemically instable because of its inclusion of solvent (such as water) when crystallized. The chemically instability of solvated lansoprazole is attributed to proton attack of lansoprazole at the sulfur atom resulting in the appearance of its derivatives, the sulfide derivative 2-[[3-methyl-4-(2,2,2-trifluorethoxy)-2-pyridinil]thio]-1H benzimidazole and the sulfone derivative 2-[[3-methyl-4-(2,2,2-trifluorethoxy)-2-pyridinil]sulfonyl]-1H benzimidazole, which are considered impurities. The presently claimed invention is directed

to lansoprazole which is stable, i.e. is less prone to chemically instability, either comprising 500 ppm to 3000 ppm water, 300 ppm and 5000 ppm alcohol or a combination thereof, and the specification specifically discloses the claimed compound and compositions. None of the cited references, taken alone or in combination, disclose or suggest the chemically stable lansoprazole composition of the presently claimed invention.

As discussed above, Vrečer discloses the relative physical stability of polymorphic forms A and B of lansoprazole. In particular, Vrečer discloses that lansoprazole polymorphic form B is not physically stable, and transforms to polymorphic form A on heating. However, Vrečer does not disclose or suggest a chemically stable lansoprazole composition, as presently claimed.

Kotar discloses the analysis of the lansoprazole polymorphs, and that lansoprazole form B is not stable, undergoing a solid-solid transition to form A. Kotar does not disclose or suggest the presently claimed chemically stable lansoprazole composition.

Choi discloses a process for preparing conventional prior art sulfoxide compounds, such as lansoprazole, comprising oxidizing a sulfide compound with hydrogen peroxide in the presence of a rhenium catalyst. Choi discloses only non-stable, prior art lansoprazole, produced with the disclosed process, and, thus, does not disclose or suggest the presently claimed chemically stable lansoprazole composition.

Nohara discloses benzimidazoles and processes for preparing such compounds. The disclosed compounds are not the chemically stable lansoprazole composition of the presently claimed invention. Instead, Nohara discloses only non-stable, prior art, lansoprazole. Therefore, Nohara does not disclose or suggest the presently claimed chemically stable lansoprazole composition.

Kato discloses a substantially solvent-free lansoprazole that is free of decomposition in the course of vacuum drying. Kato does not disclose or suggest a lansoprazole, having chemical stability over three to six months, as does the presently claimed chemically stable lansoprazole composition. The 0.03 moles of ammonia per mole of lansoprazole used in the Kato examples is only a trace amount, and is not sufficient to provide a chemically stable lansoprazole. As discussed above and at page 2 of the present specification, the lansoprazole prepared by the processes disclosed by Kato will be chemically unstable. Therefore, Kato does not disclose or suggest the presently claimed chemically stable lansoprazole composition.

Avrutov discloses processes for preparing substituted 2-(2-pyridylmethyl)sulfinyl-1-H-benzimidizoles. Avrutov discloses only non-stable, prior art lansoprazole, and does not disclose or suggest the chemically stable lansoprazole composition of the presently claimed invention.

As stated in the Office Action at page 4, Hableblian, Muzaffar, Jain, and Taday each teach that some crystalline compounds can exist in different crystalline forms. The Office Action also states, at page 4, that C & E News, Muzaffar, U.S. Pharmacopia, and Concise Encyclopedia of Chemistry all teach that, at any particular temperature and pressure, only one crystalline form is thermodynamically stable.

However, as discussed above, the presently claimed invention is directed to a chemically stable lansoprazole composition, not a thermodynamically stable polymorphic form. None of the cited references whether taken alone or in combination, disclose or suggest the presently claimed chemically stable lansoprazole composition. Instead, the cited prior art references discloses only non-stable, prior art lansoprazole.

Therefore, as the cited references, whether taken alone or in combination do not disclose or suggest the presently claimed invention, the claims are not obvious over these references. Accordingly, it is respectfully requested that the Examiner withdraw the rejection of claims 1 to 7 and 29 to 38 under 35 U.S.C. §103(a).

3. Claims 29-38 were rejected under 35 U.S.C. 112, first paragraph.

Claims 29 to 38 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement, for the reasons set forth on pages 5 to 10 of the Office Action.

In particular, the rejection is based on the possibility of a change in polymorphic state of a crystalline form of a compound during storage or tablet preparation. The Office Action, at page 6, states

> The specification lacks description of how the pharmaceutical composition can be prepared in order to maintain the particular compound of a particular form with the particular infrared and x-ray diffraction being claimed .... Disclosure of x-ray diffraction patterns for the compounds and pharmaceutical compositions comprising the polymorphic forms are lacking in the specification. The specification has also not described how the stable form and composition's being claimed will be maintained and prevented from converting to other forms .....

Further, according to the Examiner, "Applicants merely assert that the instant compounds are not polymorphs. However, the instant compounds behave similar to polymorphs." Moreover, the Examiner asserts that "contra to applicants' arguments ..... the specification lacks description and enablement that the pharmaceutical compositions contain the "stable form" without transformation."

In response, Applicants again respectfully submit that XRD and IR spectra are not provided, and there is no teaching in the specification on how to maintain a particular polymorphic form because a new polymorphic crystalline form of lansoprazole is not disclosed or claimed in the present application. The presently claimed invention is directed to a chemically stable lansoprazole. That is, the presently claimed invention is a lansoprazole, produced in a known process, that is then stabilized with the method of the invention, providing the chemically stable lansoprazole of the invention. As the present claims are not directed to a new polymorphic crystalline form, no XRD or IR spectral data are required. No disclosure of how to prevent the lansoprazole of the invention from converting to a different polymorphic form is provided, because the invention is not directed to a polymorphic form.

At pages 1 to 3, the present specification discusses the instability of prior art lansoprazole. As will be understood by one of ordinary skill in the art, the instability of lansoprazole discussed in the specification is not a polymorphic instability. Instead, the instability discussed in the specification is a chemical instability, the conversion of the lansoprazole compound to other chemical compounds such as its sulfide or sulfone derivative. When prior art lansoprazole is stored or exposed to heat and humidity, a chemical change occurs, producing impurities in the form of different chemical compounds, not different polymorphic forms. At page 3, lines 2 to 12, the present specification states that during storage, prior art lansoprazole degrades, such that the concentration of lansoprazole decreases, resulting in discoloration. Contrary to the Examiner's assertions, this chemical change that may occur is very different from the (structural) change that may occur when processing a chemical compound in preparing a pharmaceutical composition. Thus, degradation of a compound results from a chemical change, not a change in polymorphic form, as alleged in the Office Action.

Moreover, the present specification clearly teaches one of ordinary skill in the art how to make and use the invention, and the specification describes the claimed subject matter in

such a way as to reasonably covey to one skilled in the relevant art that the Applicants had possession of the claimed invention at the time the application was filed.

In the first paragraph of the Detailed Description on page 7, the specification discloses the impurities that are formed in lansoprazole during storage. The impurities are further disclosed in Tables 1 and 2 on pages 13 and 16 of the specification, respectively. Processes for preparing the presently claimed chemically stable lansoprazole are set forth in both the Summary and Detailed Description sections of the specification, and are particularly exemplified in Examples 2 and 3 on pages 12 to 14 of the specification. The superior chemical stability of the presently claimed chemically stable lansoprazole, compared to prior art lansoprazole, is set forth in the aforementioned Tables 1 and 2.

Clearly, one of ordinary skill in the art would understand how to make and use the presently claimed invention from the present specification.

With respect to an alleged lack of description as to whether the pharmaceutical carriers are able to maintain the presently claimed chemically stable lansoprazole in the stable form claimed, one of ordinary skill in the art, from the present specification, would understand how to make and use the presently claimed pharmaceutical compositions. Pharmaceutical carriers, diluents, disintegrates, binders, giants, dyes, colorants, lubricants, excipients, and the like, useful in the invention, are set forth on pages 9 to 12.

Therefore, as the presently claimed invention is not directed to stable polymorphs, but, instead, is directed to a chemically stable lansoprazole compound, the present specification clearly teaches one of ordinary skill in the art how to make and use the claimed invention, and, thus, the claims meet the requirements of 35 U.S.C. §112, first paragraph. Accordingly, it is respectfully requested that the Examiner withdraw the rejection of claims 29 to 38 under 35 U.S.C. § 112, first paragraph.

4. Claims 1-7 and 29-38 were rejected under 35 U.S.C. 112, second paragraph for being indefinite.

Claims 1-7 and 29-38 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for the reasons set forth on pages 8-10 of the Office Action.

According to the Examiner, claims 33-35 are improper product-by-process claims, as such claims are improper in the same application where it has been demonstrated that the compound in question may be described by means of a chemical structure.

In response Applicants submit that claims 33-35 are directed to a stable lansoprazole. Lansoprazole, is an active pharmaceutical ingredient which may include some amount of other chemical compounds, other than the pure chemical compound lansoprazole, such as the previously described impurities. Although the chemical compound 2-[[[3-methyl-4-(2,2,2-trifluorethoxy)-2-pyridinyl]methyl]sulfinyl]-1H benzimidazole (lansoprazole) can be described by its chemical structure the presently claimed stable lansoprazole, which comprises the chemical compound lansoprazole and small amounts of impurities, may not be readily described by the chemical structure of the compound. Further, the level of impurities and the chemical stability of the claimed lansoprazole is a result of the claimed process. For these reasons, Applicants submit that product-by-process claims 33-35 are proper.

According to the Examiner, the expression "comprising" and "further comprising" in claims 1-7 and 29-38 are open ended and allow for the inclusion of other parameters not contemplated by Applicant. Applicants understand this to mean that a compound has a specific structure that cannot be modified without changing the compound to a different compound. The Examiner has apparently defined the claimed stable lansoprazole as chemically pure lansoprazole.

In response, as discussed above, Applicants submit and reiterate that one of ordinary skill in the art would understand that any given sample of the active pharmaceutical ingredient lansoprazole contains lansoprazole and some amount of impurities. One of ordinary skill in the art would understand that it is virtually impossible for any given sample of lansoprazole to be 100 percent pure lansoprazole. Instead, a sample of lansoprazole also contains lansoprazole and trace amounts of water and/or alcohol, in addition to trace amounts of other impurities, and, thus, is effectively a lansoprazole composition, even where the lansoprazole is of a very high purity. Even with the presently claimed stable lansoprazole compound, it is practically impossible to remove all impurities, although the rate at which the amount of any impurities in the presently claimed stable lansoprazole composition increases is significantly slower during storage than the rate at which impurities are formed in prior art lansoprazole. For these reasons, one of ordinary skill in the art would understand that the "stable lansoprazole compound" of the present invention, as recited in the originally filed claims, is actually a chemically stable lansoprazole compound that contains trace amounts of impurities, such as the water and alcohol recited in claims 1, 3, and 5 and the sulfone and sulfide derivatives recited in claims 6 and 34. It would also be understood by one of ordinary

skill in the art that any bulk sample of lansoprazole would most likely also contain at least trace amounts of impurities other than those recited in the claims. Accordingly, Applicants did contemplate the inclusion of other parameters not recited in the claims. Thus, the present claims are open ended, but still meet the requirements of 35 U.S.C. § 112. As noted above, one of ordinary skill in the art would understand that the originally claimed "stable lansoprazole compound" was a composition comprising lansoprazole, water and/or alcohol, and other trace impurities, and, thus, the presently claimed stable lansoprazole composition is fully supported by the application and claims, as originally filed.

With regard to the recitation of sulfone derivative and sulfide derivative in claims 6 and 34, the Examiner asserts these terms are indefinite to their meaning. Although Applicants believe that those terms are clearly defined at the first paragraph of page 2, and page 6, lines 7-9, and in Tables 1 and 2 on pages 13 and 16 of the specification, and, thus, would be understood by one of ordinary skill in the art, Applicants have amended claims 6 and 34 reciting the sulfone and sulfide derivative to more clearly define the claimed subject matter.

According to the Examiner claims 29-38 are improper composition claims because they fail to recite the presence of an inert carrier. In response, Applicants submit that claims 29, 31, and 33 each recite that the claimed pharmaceutical compositions comprises a pharmaceutically acceptable excipient. By definition, an excipient is a substance used as a diluent or carrier for a drug. Claims 30, 32, and 34-38 are dependent therefrom and therefore incorporate the same element of a pharmaceutical acceptable excipient. Therefore, the claims are directed to compositions comprising a carrier.

With regard to the recitation of the term "lansoprazole" in claims 1-7 and 29-38, the Examiner asserts that where the generic name lansoprazole is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with 35 U.S.C. § 112, second paragraph. The Examiner cites *Ex Parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). According to the Examiner the claim scope is uncertain since the generic name cannot be used to properly identify any particular material or product. The Examiner asserts that a generic name is used to identify a source of goods, and not the goods themselves.

In response, Applicants submit that contrary to the Examiner's assertions a generic name does not identify a source of goods, but identifies the goods themselves. The Examiner

has confused the terms "generic name" and "trade name." A "trade name" identifies a source of goods. The term "lansoprazole" is not a trade name but a generic name for the chemical entity. Lansoprazole is an active pharmaceutical ingredient marketed under the trade name PREVACID in the United States. For this reason, Ex Parte Simpson, cited by the Examiner, does not apply as it relates to the use of trade names. Applicants submit that the term lansoprazole identifies an active pharmaceutical ingredient regardless of its source and therefore clearly identifies and describes the claimed subject matter in claims 1-7 and 29-38.

Therefore, the claims particularly point out and distinctly claim the subject matter Applicants regard as the invention. Accordingly, it is respectfully requested that the Examiner withdraw the rejection of claims 1 to 7 and 29 to 38 under 35 U.S.C. §112, second paragraph.

5. Claims 1-7 and 29-38 were provisionally rejected under the judicially created doctrine of obviousness type double patenting.

Claims 1-7 and 29-38 are provisionally rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 33-38 and 42-45 of copending U.S. Application Ser No. 10/773,535 in view of Haleblian et al., Chemical & Engineering News, US Pharmacopeia, Muzaffar et al, Jain et al, Taday et al, and Concise Encyclopedia Chemistry. According to the Examiner the stable compound and compositions are disclosed in this copending application. In response, Applicants wish to defer filing a terminal disclaimer until the currently pending claims are deemed allowable, at which time, Applicants intend to file a terminal disclaimer.

Applicants thus submit that the entire application is now in condition for allowance, an early notice of which would be appreciated. Should the Examiner not agree with Applicants' position, a personal or telephonic interview is respectfully requested to discuss any remaining issues prior to the issuance of a further Office Action, and to expedite the allowance of the application.

A separate Petition for Extension of Time is submitted herewith. Should any additional fees be due, however, please charge such fees to Deposit Account No. **11-0600**.

Respectfully submitted,

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Dated: July 13, 2007

By: _____

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